No. 25-1619

UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

NOVARTIS PHARMACEUTICALS CORPORATION,
Plaintiff-Appellant,

v.

ANDREW BAILEY, in his official capacity as Attorney General of the state of Missouri, *ET AL.*,

Defendants-Appellees,

and

MISSOURI HOSPITAL ASSOCIATION AND MISSOURI PRIMARY CARE ASSOCIATION,

Intervenors-Appellees.

On appeal from the United States District Court
for the Western District of Missouri
No. 2:24-cv-04131-MDH,
District Judge M. Douglas Harpool

BRIEF OF AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS AS *AMICI CURIAE* IN SUPPORT OF APPELLEES AND AFFIRMANCE

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CORPORATE DISCLOSURE STATEMENT

The American Hospital Association is a non-profit organization that does not have a parent corporation. It does not issue stock.

340B Health is a non-profit organization that does not have a parent corporation. It does not issue stock.

The American Society of Health-System Pharmacists is a non-profit organization that does not have a parent corporation. It does not issue stock.

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INTERESTS OF *AMICI CURIAE*[1]

Proposed *Amici* include two hospital associations with members in Missouri that receive 340B discounts for drugs that they purchase, many of which are dispensed through contract pharmacies, and one organization that represents pharmacists who serve patients in hospitals, health systems, ambulatory clinics, and other healthcare settings many of which benefit from the 340B program. *Amici* and their members are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care. The discounts provided by the 340B program are essential to achieving this goal. *Amici* therefore have a strong interest in the success of Missouri legislative efforts to protect the 340B program.

The **American Hospital Association** (AHA) represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations nationwide. AHA members are committed to helping ensure that healthcare is available to and affordable for all Americans. AHA promotes the interests of its members by participating as *amicus curiae* in cases with important and far-ranging consequences for their members, including cases related to the 340B program.

[1] No party's counsel authored this brief in whole or in part. No one other than *Amici* or their counsel contributed any money to fund its preparation or submission. The parties all consent to the filing of this brief.

340B Health is a national, not-for-profit organization founded in 1993 to advocate for 340B hospitals—a vital part of the nation's healthcare safety net. 340B Health represents over 1,600 public and private nonprofit hospitals and health systems participating in the 340B program.

The **American Society of Health-System Pharmacists** (ASHP) is the largest association of pharmacy professionals in the United States. ASHP advocates and supports the professional practice of pharmacists in hospitals, health systems, ambulatory care clinics, and other settings spanning the full spectrum of medication use. For over 80 years, ASHP has championed innovation in pharmacy practice; advanced education and professional development; and served as a steadfast advocate for members and patients.

INTRODUCTION

Five years ago, nearly 40 drug companies, including Appellant Novartis Pharmaceuticals Corporation ("Novartis"), broke with decades of precedent and suddenly refused to ship drugs purchased by 340B hospitals to contract pharmacies. The contract pharmacy arrangements that drug companies like Novartis honored for almost thirty years helped sustain hospitals and their patients. The federal government determined that this was unlawful and sought to require manufacturers

to continue delivering these drugs to contract pharmacies on the same terms to which they delivered those drugs to 340B in-house hospital pharmacies.[2]

"Section 340B, 42 U.S.C. § 256b, requires pharmaceutical manufacturers to offer discounted drugs to covered entities for purchase. It is *silent* as to whether manufacturers must deliver those drugs to contract pharmacies." Br. for Appellee Novartis Pharms. Corp. at 4, *Novartis Pharms. Corp. v. Johnson*, No. 21-5299, 2022 WL 2072941 (D.C. Cir. June 8, 2022).[3] Novartis submitted these exact words to the United States Court of Appeals for the D.C. Circuit only three years ago when faced with the federal government's attempt to penalize the company's harsh restrictions on contract pharmacy arrangements.

In lawsuit after lawsuit, at no point did Novartis or its sister drug companies describe their contract pharmacy policies as price restrictions. Instead, they insisted that their policies were permissible because (1) they were *delivery* restrictions, and (2) the 340B statute had absolutely nothing to say about *delivery*. Those arguments

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[2] *See, e.g.*, Letter from Dep't of Health & Hum. Servs., Health Resources & Servs. Admin. Administrator C. Johnson to AbbVie, Inc. Vice Pres., U.S. Market Access C. Compisi (Oct. 17, 2022), https://www.hrsa.gov/sites/default/files/hrsa/opa/programintegrity/hrsa-letter-abbvie-covered-entities.pdf.

[3] *See also* AstraZeneca Opening Br. at 4, *AstraZeneca Pharms. L.P. v. U.S. Dep't of Health & Hum. Servs.*, No. 22-01676 (3d Cir. July 21, 2022) ("Section 340B is 'silent' on the role of contract pharmacies under the program. That silence means the statute does not impose contract pharmacy obligations on manufacturers.").

carried the day. *See Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024) (Section 340B is "silent about delivery conditions"); *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 703 (3d Cir. 2023) (Section 340B's "text is silent about delivery").

Like many other states, Missouri has filled the federal statutory gap that drug companies spent years fighting for by requiring drug companies to ship drugs to 340B entities' contract pharmacies on the same terms as they ship those drugs to 340B entities' in-house pharmacies. Faced with the drug industry's unprecedented assault on Missouri's health care safety net and the acknowledged gap in federal law, the Missouri legislature acted. Codified at § 376.414.2 (2024), Mo. Rev. Stat., Senate Bill 751 (S.B. 751) provides that drug manufacturers:

> shall not deny, restrict, or prohibit, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with, or otherwise authorized by a, covered entity to receive 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services.

S.B. 751 also provides that "[n]othing in this section shall be construed or applied to be in conflict with . . . [a]pplicable federal law and related regulation[.]" *Id.* § 376.414.6. S.B. 751 does only what Novartis and the federal courts said the *federal* law did not do—regulate the delivery of 340B drugs. Mo. Rev. Stat. § 376.414.2.

Now comes the whiplash. Banking its prior win, Novartis now claims that S.B. 751 is a pricing—not delivery—statute. Although Missouri has legislated in

precisely the area that Novartis successfully insisted was *not* addressed under federal law—the delivery of 340B drugs—the company has reversed course in this litigation to claim that S.B. 751 is preempted by federal law. And as part of that about-face, Novartis now insists that states cannot fill the federal statutory gap that drug companies (including Novartis) spent years fighting for.

This history is important—and not just because it exposes the hypocrisy in Novartis's legal position. It also serves as a reminder of *why* Missouri chose to step into the federal statutory void. Put simply, Missouri acted because drug companies and the federal courts all but invited it to do so.

The primary issue here is whether Missouri, exercising its historic police power over health and safety, can fill the gap in the federal 340B statute and regulate the delivery of 340B drugs (purchased by 340B hospitals) to contract pharmacies. It can. Numerous district courts have said so,[4] as has this Court in the only Court of Appeals decision to date addressing a drug industry challenge to a state contract

[4] *See Novartis Pharms. Corp. v. Fitch*, 738 F. Supp. 3d 737 (S.D. Miss. 2024), *appeal docketed*, No. 24-60342 (5th Cir. July 9, 2024); *AstraZeneca Pharms. LP v. Bailey*, No. 2:24-cv-4143-MDH, 2025 WL 644285 (W.D. Mo. Feb. 27, 2025); *AstraZeneca Pharms. LP v. Fitch*, No. 1:24-cv-196-LG-BWR, 2024 WL 5345507 (S.D. Miss. Dec. 23, 2024); *Pharm. Rsch. & Mfrs. of Am. v. Murrill*, No. 6:23-cv-00997, 2024 WL 4361597 (W.D. La. Sept. 30, 2024) (*PhRMA v. Murrill*), *appeal docketed*, No. 24-30673 (5th Cir. Oct. 21, 2024); *AbbVie Inc. v. Fitch*, No. 1:24-cv-184-HSO-BWR, 2024 WL 3503965 (S.D. Miss. July 22, 2024), *appeal docketed*, No. 24-60375 (5th Cir. July 24, 2024); *Pharm. Rsch. & Mfrs. of Am. v. Fitch*, No. 1:24-cv-00160-HSO-BWR, 2024 WL 3277365 (S.D. Miss. July 1, 2024), *appeal docketed*, No. 24-60340 (5th Cir. July 5, 2024).

pharmacy statute. *See PhRMA v. McClain*, 95 F.4th 1136, 1143–45 (8th Cir.), *cert. denied*, 145 S. Ct. 768 (2024).

Bringing claims foreclosed by *PhRMA v. McClain* and *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023), Novartis now seeks to halt Missouri's lawful exercise of its police power to protect public health and safety. This Court should rebuff that effort. The district court correctly found that Novartis did not demonstrate that it was entitled to a preliminary injunction because it is unlikely to succeed on the merits of *any* of its claims.

FACTUAL BACKGROUND AND SUMMARY OF ARGUMENT

Novartis spends page after page maligning the 340B Program and the covered entities that rely on it. Needless to say, it is in its financial interest to do so. For Novartis, every 340B drug it refuses to deliver to a Missouri contract pharmacy is an additional profit line on its balance sheets.

But this is not how the Supreme Court has viewed the program. As Justice Kavanaugh wrote for a unanimous Supreme Court just a few years ago: "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738 (2022). And more significant here, the Missouri legislature, with an unbiased interest in protecting its citizens, hospitals, and pharmacies, shares the Supreme Court's view of the Program. When enacting S.B. 751, the Missouri

legislature rejected the drug companies' efforts to denigrate the 340B Program and those who rely on it.

For good reason. The contract pharmacy arrangements that Novartis honored for almost 30 years helped sustain hospitals and their patients. Nationwide, a quarter of hospitals' 340B benefit comes from drugs dispensed at contract pharmacies.[5] For rural Critical Access Hospitals, savings from partnerships with these pharmacies represented an average of 52% of overall 340B savings.[6] Of the 73 Missouri hospitals participating in the 340B drug program, 71 contract with at least one community pharmacy to dispense drugs to patients.[7]

The drug company restrictions have substantially cut the savings from the 340B program, which is devasting for hospitals in Missouri that provide 77% of all hospital care that is provided to Medicaid patients.[8] For example, Golden Valley

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[5] 340B Health, *Restrictions on 340B Contract Pharmacy Increase Drug Company Profits but Lead to Lost Savings, Patient Harm, and Substantial Burden for Safety-Net Hospitals* 8, https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_March_2023.pdf.

[6] 340B Health, *Restrictions on 340B Contract Pharmacy Increase Drug Company Profits but Lead to Lost Savings, Patient Harm, and Substantial Burden for Safety-Net Hospitals* 8 (Mar. 2023), https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_March_2023.pdf.

[7] Health Res. & Servs. Admin, Off. of Pharmacy Affairs, *340B OPA Info. Sys.*, https://340bopais.hrsa.gov/coveredentitysearch.

[8] Dobson DaVanzo Health Economics Consulting, *Missouri 340B Hospitals Serve More Patients With Low Incomes, Who Live With Disabilities, and/or Identify as*

Memorial Healthcare (GVMH), which has facilities in Clinton, Warsaw, Windsor, and Osceola, uses 340B savings to provide critical healthcare services—including a diabetes management program, birthing center, and ambulance services—to rural communities.[9] GVMH relies entirely on its savings from the 340B program to subsidize its diabetes program, which entails not only diabetes care and medication but also patient education and counseling. Further, GVMH's patients have suffered the consequences of drug company greed. Last year, the restrictive contract pharmacy policies of drug companies like Novartis forced GVMH to reduce the number of available maternity beds.[10]

Contract pharmacy arrangements are especially important because fewer than half of 340B hospitals operate in-house pharmacies.[11] This is why 340B hospitals have relied on contract pharmacies since the beginning of the program.[12] In addition,

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Black 2, 340B Health, https://www.340bhealth.org/files/MO-340B-Low-Income15023.pdf.

[9] Craig Thompson, *Opinion: 340B: Preserving Access to Hospital Care*, Missouri Times (Feb. 12, 2024), https://themissouritimes.com/opinion-340b-preserving-access-to-hospital-care/.

[10] *Id.*

[11] 340B Health, *Drugmakers Pulling $8 Billion Out of Safety-Net Hospitals: More Expected as Growing Number Impose or Tighten 340B Restrictions* (July 2023), https://www.340bhealth.org/files/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf.

[12] *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Contracted Pharmacy Services, 60 Fed. Reg. 55,586 (Nov. 1, 1995).

the restrictive drug manufacturer policies do not recognize that payors and pharmacy benefit managers (PBMs) influence where patients must fill their prescriptions. For example, many payors require that certain specialty drugs be filled only at a PBM-owned "specialty pharmacy." Such "specialty" drugs are typically used to treat chronic, serious, or life-threatening conditions, and are often priced much higher than non-specialty drugs.[13] Only one in five 340B hospitals have in-house "specialty" pharmacies. Thus, 340B hospitals typically *must* contract with at least one specialty pharmacy to receive the 340B discount for their patients' high-priced specialty drugs.[14] In fact, for seven of the 21 drug companies with restrictive contract pharmacy policies as of June 1, 2023, specialty drugs make up more than three-quarters of the savings associated with restricted drugs.[15]

Savings from contract pharmacy relationships are especially important for another reason: the fragile state of 340B hospital finances. In stark contrast to the pharmaceutical industry, 340B hospitals typically operate with razor-thin (and often

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[13] Adam J. Fein, *Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?*, Drug Channels Institute (Dec. 12, 2019), https://www.drugchannels.net/2019/12/insurers-pbms-specialty-pharmacies.html; U.S. Dep't of Health & Hum. Servs. Off. Of Inspector Gen., *Specialty Drug Coverage and Reimbursement in Medicaid*, https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000255.asp.

[14] 340B Health, *supra* note 11, at 7 (citing Fein, *supra* note 13).

[15] 340B Health, *supra* note 11, at 6.

negative) margins.[16] This is not surprising: 340B hospitals provide a disproportionate amount of uncompensated care to the country's most vulnerable patients.[17] Savings from the 340B program help to offset the cost of providing uncompensated health care.

ARGUMENT

This Court should affirm the district court's well-reasoned ruling. *First*, Novartis's preemption claim is foreclosed by *PhRMA v. McClain*, and this Court should reject Novartis's brazen attempt to circumvent that binding precedent. Congress did not create or occupy any field through its 340B legislation, nor does it conflict with the 340B statute. At bottom, Novartis takes the position that whenever Congress creates a detailed federal program, that comprehensiveness wrests traditional police power from the States. That has never been the rule in our federal system. To the contrary, as this Court has explained, "[p]harmacy has traditionally been regulated at the state level, and [courts] must assume that absent a strong

[16] AHA, *340B Drug Pricing Program: Fact vs. Fiction* 3 (Apr. 2023), https://www.aha.org/system/files/2018-04/340BFactvsFiction.pdf; Allen Dobson *et al.*, *The Role of 340B Hospitals in Serving Medicaid and Low-income Medicare Patients* 12–13 (July 10, 2020), https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf.

[17] *See* L&M Policy Research, LLC, *Analysis of 340B Disproportionate Share Hospital Services to Low-Income Patients* 1 (Mar. 12, 2018); AHA, *supra* note 16, at 3; Dobson, *supra* note 16, at 13–17.

showing that Congress intended preemption, state statutes that impact health and welfare are not preempted." *PhRMA v. McClain*, 95 F.4th at 1144 (citing *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021)); *see MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1023 (5th Cir. 1994). For this reason, courts around the country have routinely rejected preemption challenges to analogous state statutes brought by Novartis and other manufacturers. *See, e.g.*, *Novartis v. Fitch*, 738 F. Supp. 3d at 747; *PhRMA v. Fitch*, 2024 WL 3277365, at *8; *AbbVie v. Fitch*, 2024 WL 3503965, at *7; *PhRMA v. Murrill*, 2024 WL 4361597, at *9; *AstraZeneca v. Fitch*, 2024 WL 5345507, at *4–9. As discussed below, moreover, the single decision overturning a state law protecting 340B contract pharmacies, *Pharm. Rsch. & Mfrs. of Am. v. Morrisey*, Nos. 2:24-cv-00271, 2:24-cv-00272, 2:24-cv-00298, 2024 WL 5147643 (S.D. W. Va. Dec. 17, 2024) (*PhRMA v. Morrisey*), *appeal docketed*, Nos. 25-1054, 25-1055, 25-1056 (Jan. 16, 2025), was based on a fundamental misunderstanding of the 340B statute and program.

Second, the Missouri statute is not an unconstitutional extraterritorial regulation. The sweeping reading of the dormant Commerce Clause advanced by Novartis was recently rejected by the Supreme Court. *Nat'l Pork Producers*, 598 U.S. at 375. Like the petitioners there, Novartis advocates an "'almost *per se*' rule against laws that have the 'practical effect' of 'controlling' extraterritorial commerce

[which] would cast a shadow over laws long understood to represent valid exercises of the States' constitutionally reserved powers." *Id.*[18]

I. NOVARTIS IS NOT LIKELY TO SUCCEED ON THE MERITS OF ITS PREEMPTION CLAIMS.

A. Novartis's Preemption Claim is Foreclosed by *PhRMA v. McClain*.

Novartis's preemption claim runs headlong into this Court's well-reasoned and controlling opinion in *PhRMA v. McClain*. In that case, this Court rejected the pharmaceutical manufacturing association's contentions that the 340B program preempts the field, that the analogous Arkansas statute directly conflicts with the federal 340B statute, and that the State statute made it impossible to comply with 340B. *First*, explaining that "[t]he case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts," this Court held that "Congressional silence on pharmacies in the context of 340B indicates that Congress did not intend to preempt the field." *PhRMA v. McClain*, 95 F.4th at 1144 (internal citation omitted). *Second*, this Court found that the Arkansas law "does not create an obstacle for pharmaceutical manufacturers to comply with 340B, rather it does the opposite: Act 1103 assists in fulfilling the purpose of 340B." *Id.* at 1144–

[18] For the reasons set forth in Defendants-Appellees' Brief at 54–59 and 68, the district court also correctly ruled that a preliminary injunction of S.B. 751 would not serve the public interest and that Novartis would not suffer irreparable harm from enforcement of S.B. 751.

45. *Third*, this Court found no impossibility preemption in light of the U.S. Food and Drug Administration's Risk Evaluation and Mitigation Strategy requirements because "[j]ust because a medication is subject to multiple legal requirements does not make it impossible to comply with" the State law. *Id.* at 1145. *PhRMA v. McClain* disposes of each of Novartis's 340B preemption claims.

Novartis's contentions to the contrary rely on a blatant misreading of two cases that confirmed that the federal 340B statute was silent with respect to delivery. Neither *Novartis Pharmaceuticals Corp. v. Johnson* nor *Sanofi Aventis U.S. LLC v. H.H.S.* held that the federal 340B statute was "drafted to preserve a manufacturer's right to limit distribution to a *single* contract pharmacy at the covered entity's choosing." *See* Novartis Br. at 48. Rather, at Novartis's urging, the Third Circuit and D.C. Circuit both accepted Novartis's argument that 340B's statutory silence does not prohibit manufacturers from limiting sales of 340B drugs dispensed through contract pharmacies. *See Novartis v. Johnson*, 102 F.4th at 460 (Section 340B is "silent about delivery conditions"); *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th at 703, 707 (Section 340B's "text is silent about delivery" and "[l]egal duties do not spring from silence."). Novartis now inconsistently contends that statutory silence precludes state action. Novartis cannot have it both ways. Neither the Third nor D.C. Circuit said anything about what *States* may do in

the face of the federal law's "silence." Novartis cannot spin this statutory silence into preemptive substance.[19]

B. The Lone Court to Find Preemption Did So on the Basis of Flawed Legal Analysis and a Misunderstanding of the 340B Statute and Program.

Tellingly, only one district court to consider a preemption challenge to an analogous state statute has sided with the manufacturers. The West Virginia district court's preliminary injunction ruling that that State's contract pharmacy law is likely preempted both ignores the presumption against preemption, *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and is based on a flawed interpretation of the federal 340B statute and how the program operates. That outlier decision should carry no weight with this Court, just as it was rejected by the Southern District of Mississippi only days later. *AstraZeneca v. Fitch*, 2024 WL 5345507, at *9 (refusing to "disregard mainstream decisions and the Eighth Circuit's ruling in *McClain* without clear precedential support").

In an opinion replete with mischaracterizations of the 340B program and how it operates, the West Virginia court wrongly concluded that its state statute regulated 340B drug price and not delivery. The court stated that under the replenishment model, "[b]ecause the drug is already in the hands of the contract pharmacy even

[19] Further, for the reasons set forth in Defendants-Appellees' Brief at 64–68, Novartis is incorrect in arguing that *PhRMA v. McClain* was wrongly decided.

before the patient arrives at the pharmacy, the question is not about the delivery of the drug." *PhRMA v. Morrisey*, 2024 WL 5147643, at *8. But this puts form over substance.

The "replenishment model" is simply an inventory management system that tracks patient and drug data to ensure that 340B hospitals only pay the 340B price for drugs received by their eligible patients. *See, e.g.*, *AbbVie v. Fitch*, 2024 WL 3503965, at *14 (the replenishment model merely "relies on pharmaceuticals' fungibility to facilitate efficiency"). If a contract pharmacy received each 340B drug at the 340B price and then dispensed the drug, one-by-one, directly to the patient at the contract pharmacy, the West Virginia court would logically have had to conclude that the law did not regulate price because the price was set by the 340B statute. The only difference with the replenishment model is that the drug is dispensed at a contract pharmacy and is then replenished. This is an inventory management method that avoids the necessity of having two separate supplies of the same drug, one for 340B patients and one for other patients.[20]

In both cases, the price is set by federal statute and in neither case is the State law establishing the price. All the State law is doing is ensuring that drug companies

[20] Both the Supreme Court and the Federal Trade Commission have blessed replenishment models in other contexts. *See Abbott Labs. v. Portland Retail Druggists Ass'n, Inc.*, 425 U.S. 1 (1976); Letter from F.T.C. Ass't Dir. Markus H. Meier to Kathleen A. Reed re: University of Michigan Advisory Opinion (Apr. 9, 2010), https://perma.cc/JX3M-9J3V.

continue to deliver drugs to contract pharmacies, where those drugs can be dispensed to 340B patients on equal terms as if they were delivered to and dispensed at hospital pharmacies. Indeed, drug manufacturers do not refuse to ship 340B drugs to hospital pharmacies that use the same replenishment model. All the State law allows for is the hospital to warehouse the drug at a contract pharmacy using the replenishment model as an inventory management system. Thus, by refusing to deliver to those contract pharmacies, the drug companies are imposing *delivery* restrictions—namely, they are saying, "We will deliver to your hospital but not your functional warehouse that makes it easier to get those drugs into the hands of needy patients."

Ultimately, the only impact of state laws like West Virginia's and Missouri's is to ensure that manufacturers deliver 340B drugs purchased by the 340B covered entity at the federally-mandated price, regardless of whether the covered entity is using an in-house pharmacy or an outside pharmacy. The West Virginia court failed to understand that this is a question of delivery rather than price.

II. S.B. 751 DOES NOT VIOLATE THE DORMANT COMMERCE CLAUSE.

Novartis also claims that S.B. 751 runs afoul of the dormant Commerce Clause because "it regulates wholly out-of-state conduct; it discriminates against out-of-state economic interests; and it creates incidental burdens on interstate commerce that far outweigh any local benefit." Novartis Opening Br. at 33. Novartis

is wrong on all three counts; its dormant Commerce Clause claim is squarely foreclosed by *National Pork Producers*, 598 U.S. 356.

As a factual matter, the Missouri law applies *only* to drugs dispensed to patients of *Missouri* 340B providers. Like "many (maybe most) state laws," S.B. 751 may indirectly impact "extraterritorial behavior" for companies like Novartis that are headquartered outside of Missouri, but this is permitted by *National Pork Producers*, 598 U.S. at 374. And S.B. 751 in no way targets Novartis's upstream transactions with out-of-state wholesalers. *See* Novartis Br. at 34. Rather, S.B. 751 is focused entirely on drug dispensing to patients of 340B providers that are *inside* of Missouri's borders. Even if Novartis had a valid legal theory about extraterritorial effects, it would not apply to S.B. 751 on the facts.[21] *See Nat'l Pork Producers*, 598 U.S. at 375 (quoting *Hoyt v. Sprague*, 103 U. S. 613, 630 (1880)).

But Novartis has no valid legal theory. *Pork Producers* flatly rejected the "almost *per se*" extraterritoriality rule that Novartis seeks, holding that the dormant Commerce Clause does *not* forbid "enforcement of state laws that have the "practical effect of controlling commerce outside the State[.]" *Nat'l Pork Producers*, 598 U.S. at 371. Instead, the "very core" of its dormant Commerce Clause jurisprudence is

[21] None of the cases cited by Novartis support its argument to the contrary. Rather, those cases involve state statutes directly regulating out-of-state conduct. *See, e.g.*, *Legato Vapors, LLC v. Cook*, 847 F.3d 825, 827 (7th Cir. 2017) (finding a dormant Commerce Clause violation where the state law at issue "impos[ed] detailed requirements of Indiana law on out-of-state manufacturing operations").

the "antidiscrimination principle," *i.e.*, whether a state engages in "economic protectionism" by privileging in-state competitors over out-of-state competitors. *Id.* at 369. Novartis's attempt to revive the "extraterritoriality doctrine" shortly after the Supreme Court rejected it, *id.* at 371, is foreclosed by *Pork Producers*.[22]

For the same reason, the Southern District of Mississippi rejected an extraterritoriality challenge to Mississippi's materially identical law. Applying the presumption against extraterritoriality, which also exists in Missouri, *see Tuttle v. Dobbs Tire & Auto Ctrs., Inc.*, 590 S.W.3d 307, 312 (Mo. 2019), the court found that the pharmaceutical manufacturers association was unlikely to succeed on the merits of its dormant Commerce Clause claim. *PhRMA v. Fitch*, 2024 WL 3277365, at *13 (explaining that the Mississippi law "does not exhibit a clear intent to regulate out-of-state conduct"). The same is true of S.B. 751.

Perhaps recognizing the weakness of its dormant Commerce Clause "extraterritoriality" claim, Novartis makes a last-ditch effort to save it through a misleading argument that S.B. 751 discriminates against out-of-state drug

[22] *Pork Producers* also fatally undermines Novartis's reliance on *Association for Accessible Medicines v. Frosh*, 887 F.3d 664, 674 (4th Cir. 2018). As the Supreme Court explained, *Frosh* stands for the principle that one state may not tie "the price of . . . in-state products to out-of-state prices." *Nat'l Pork Producers*, 598 U.S. at 374. S.B. 751 does no such thing. It simply requires manufacturers to distribute 340B drugs to the pharmacies with which Missouri 340B hospitals have contracted. There is no tie to prices set by any other State. That alone refutes Novartis's reliance on *Frosh*.

manufacturers. But its argument grossly misapplies the leading Supreme Court cases analyzing the dormant Commerce Clause. Critically, Novartis never disputes that S.B. 751 treats in-state and out-of-state drug manufacturers equally. *Both* are forbidden from interfering with contract pharmacy arrangements.

Faced with this insurmountable factual hurdle, Novartis attempts to distract the Court with an entirely different comparison: how S.B. 751 treats in-state 340B providers and pharmacies on the one hand and drug manufacturers on the other. But that is irrelevant to the determination of whether the statute discriminates against out-of-state businesses.

The *Pork Producers* Court's analysis of *Baldwin v. GAF Seelig, Inc*., 294 U.S. 511 (1935) is illustrative. In *Baldwin*, the Court considered the constitutionality of applying a New York statutory price control on milk to a dealer in interstate commerce. As *Pork Producers* explained, "the challenged laws [in *Baldwin*] deliberately robbed *out-of-state dairy farmers* of the opportunity to charge lower prices in New York thanks to whatever natural competitive advantage they might have enjoyed over *in-state dairy farmers*." *Nat'l Pork Producers*, 598 U.S. at 371–72 (emphasis added). Novartis's clumsy effort to elide this precedent demonstrates the weakness of its argument. Put simply, S.B. 751 does not discriminate against out-of-state drug manufacturers and does not run afoul of any antidiscrimination principle set forth in the Supreme Court's dormant Commerce Clause jurisprudence.

Finally, Novartis is incorrect that *Pike v. Bruce Church Inc.*, 397 U.S. 137 (1970), supports its position. As the petitioners in *Pork Producers* contended, Novartis argues that the Court should evaluate whether "the burdens imposed on interstate commerce are 'clearly excessive in relation to the putative local benefits.'" Novartis Br. at 43 (quoting *Pike*, 397 U.S. at 142); *see Nat'l Pork Producers*, 598 U.S. at 377. But the opinions in *National Pork Producers* are clear that the *Pike* test that Novartis advocates no longer applies. In *National Pork Producers*, three Justices (Justices Gorsuch, Thomas, and Barrett) joined an opinion entirely rejecting the *Pike* analysis, *Nat'l Pork Producers*, 598 U.S. at 381–83, and two additional Justices joined an opinion stating that even assuming that *Pike* still did apply, they would require a "plaintiff to plead facts plausibly showing that a challenged law imposes 'substantial burdens' on interstate commerce *before* a court may assess the law's competing benefits." *See id.* at 393 (Sotomayor, J., concurring) (joined by Justice Kagan)). Novartis cannot show *any* burden—let alone a substantial one—on interstate commerce because S.B. 751 is focused entirely on drug dispensing to patients of 340B providers that are *inside* of Missouri's borders, and S.B. 751 applies equally to in-state and out-of-state manufacturers.

Also, in *National Pork Producers*, part of Justice Gorsuch's plurality opinion (which is controlling precedent for purposes of the petitioners' dormant Commerce Clause challenge under *Pike*) relied heavily on *Exxon Corp. v. Governor of*

Maryland, 437 U.S. 117 (1978), in which the Court rejected a dormant Commerce Clause claim where the burden imposed by a Maryland law fell "solely on interstate companies." *Id.* at 383. If the *National Pork Producers* state "law did not impose a sufficient burden on interstate commerce to warrant further scrutiny, the same must be said for" the Missouri law at issue here, which certainly applies both in-state and out-of-state. *See id.* at 384. And if all of that were not enough, it is hard to take seriously any contention that drug companies will find it "difficult to comply" with Missouri's law—a critical fact in the plurality's *Pike* analysis—given that they all honored contract pharmacy arrangements until 2020. *See id.* at 385. This alone disproves any *substantial* burden to interstate commerce that Novartis has alleged.

Further, even if the *Pike* "clearly excessive in relation to the putative local benefits" test were the appropriate test, Novartis's dormant Commerce Clause challenge would still fail. Novartis Br. at 43 (citing *Pike*, 397 U.S. at 142). For starters, Novartis does not address the proper burdens under the *Pike* test. It does not allege, for example, any additional "compliance costs" that result from Missouri's law. *See Nat'l Pork Producers*, 598 U.S. at 399 (Roberts, C.J., concurring in part and dissenting in part). To be sure, Missouri's law may impose costs on Novartis itself, but it will not affect Novartis's (or any other drug company's) transactions in *other* States or otherwise require compliance by drug companies who do not even wish to sell their product to Missouri covered entities. *Id.* at 400–02. Further,

Novartis completely ignores the local benefits of S.B. 751, *see supra* at 2–8, to patients and covered entities. *See AHA v. Becerra*, 596 U.S. at 737–39.

CONCLUSION

For the foregoing reasons and for the reasons set forth in Defendants-Appellees' Brief, this Court should affirm the judgment of the district court.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type volume limitations of Federal Rule of Appellate Procedure 32(a)(7)(B) and Local Rule 32(b) because it contains 5,116 words, excluding the parts of the brief exempted by Rule 32(f).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Rule 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in fourteen-point Times New Roman font.

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CERTIFICATE OF SERVICE

I certify that on August 27, 2025, the foregoing Brief of American Hospital Association, 340B Health, and American Society of Health-System Pharmacists as *Amici Curiae* in Support of Defendants-Appellees was filed electronically and has been served via the Court's ECF filing system in compliance with Rule 25(b) and (c) of the Federal Rules of Appellate Procedure on all registered counsel of record.

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